## **Amendment**

## In the Claims

1. (Currently amended) A method for enhancing transport of a compound across a cell membrane of comprising a lipid bilayer, comprising forming a complex comprising the compound and an effective amount of diketopiperazine (DKP) to enhance transport of the compound directly into the cell, wherein transport of the compound from the proximal face of the lipid bilayer to a distal face of the lipid bilayer is increased in the presence of the DKP compared to in the absence of the DKP,

and administering contacting the cell in vivo with the complex with a schedule resulting in substantially no increase in immune response.

- 2. (Canceled).
- 3. (Previously presented) The method of claim 1, wherein the DKP is coated with a synthetic or natural polymer.
- 4. (Currently amended) The method of claim 4 38, wherein the immune response is increased by less than 20% in the presence of DKP compared to in its absence.
- 5. (Original) The method of claim 1, wherein the compound is a biologically active agent.
- 6. (Original) The method of claim 5, wherein the biologically active agent is selected from the group consisting of insulin, an insulin precursor, Parathyroid hormone (PTH),

Calcitonin, Human Growth Hormone (HgH), Glucagon-like peptides (GLP), cytokines,

chemokines, and fragments thereof.

7. (Original) The method of claim 5, wherein the biologically active agent is an antibody

or fragment thereof.

8. (Original) The method of claim 1, wherein the diameter of the complex is less than 5

microns.

9. (Original) The method of claim 1, wherein the diameter of the complex is less than

2.5 microns.

10. (Original) The method of claim 1, wherein the diameter of the complex is between

1.5 and 2.5 microns.

11. (Original) The method of claim 3, wherein the immune response is measured by

detecting an antibody, T cell proliferation, or production of a cytokine.

12. (Original) The method of claim 11, wherein the cytokine is interleukin-2.

13. (Original) The method of claim 1, wherein DKP does not engage a toll-like receptor.

14. (Currently amended) The method of claim 1, wherein the cell is in a pulmonary

tissue or cells are contacted.

15. (Original) The method of claim 14, wherein the pulmonary tissue comprises a small

airway of the lung.

16. (Original) The method of claim 14, wherein the tissue comprises alveoli.

45072726 3 PDC 126

078374/00029

17. (Original) The method of claim 14, wherein a dose of the compound is between 0.5

and 100 milligrams per administration.

18. (Previously presented) The method of claim 14, wherein a dose of the compound is

between 500 and 1000 micrograms per administration.

19. (Original) The method of claim 14, wherein a dose of the compound is between 2

and 16 milligrams per day.

20. (Original) The method of claim 14, wherein the molecular weight of the compound

is less than 200 kDa.

21. (Original) The method of claim 14, wherein the molecular weight of the compound

is less than 100 kDa.

22. (Previously presented) The method of claim 14, wherein the molecular weight of the

compound is less than 50 kDa.

23. (Original) The method of claim 14, wherein the molecular weight of the compound

is between 3 and 6 kDa.

24. (Currently amended) The method of claim 14, wherein the composition compound is

a polypeptide.

25. (Original) The method of claim 24, wherein the amino acid sequence of the

polypeptide is identical to a naturally-occurring polypeptide expressed by a member of the

species of the mammal.

45072726 4 PDC 126

078374/00029

26. (Previously presented) The method of claim 24, wherein the polypeptide is selected

from the group consisting of insulin, an insulin precursor, Parathyroid hormone (PTH),

Calcitonin, Human Growth Hormone (HgH), Glucagon-like peptides (GLP), and fragments

thereof.

27. (Original) The method of claim 24, wherein the polypeptide is an antibody or

fragment thereof.

28. (Original) The method of claim 14, wherein the method comprises a plurality of

contacting steps.

29. (Original) The method of claim 28, wherein an interval of time between the

contacting steps is less than 24 hours.

30. (Original) The method of claim 29, wherein the interval is less than 12 hours.

31. (Original) The method of claim 29, wherein the interval is less than 6 hours.

32. (Original) The method of claim 29, wherein the interval is less than 3 hours.

33. (Original) The method of claim 28, wherein following the plurality of contacting

steps, immune cells in the pulmonary tissue are non-responsive to subsequent contact with the

compound.

34. (Currently amended) The method of claim 1, wherein the cell membrane or lipid

bilayer is located in a mammal.

35. (Original) The method of claim 34, wherein the mammal is a human.

36. (Original) The method of claim 34, wherein the complex is administered orally.

U.S.S.N. 10/632,878 Filed: August 1, 2003

## AMENDMENT AND RESPONSE TO OFFICE ACTION

Claim 37. (Canceled)

38. (New) The method of claim 1, wherein the cell is contacted with the complex in a schedule resulting in substantially no increase in the cell's immune response.